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APPLICATION NO.	F	ILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,578		11/07/2001	Prem Chandar	J6674(C)	4054
201	7590	04/09/2003			
UNILEVE	-		EXAMINER		
PATENT DE 45 RIVER R		ENT	BAHAR, MOJDEH		
EDGEWATER, NJ 07020				ART UNIT	PAPER NUMBER
				1617	7
				DATE MAILED: 04/09/2003	/

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)				
•		10/036,578	CHANDAR ET AL.				
	Office Action Summary	Examiner	Art Unit				
		Mojdeh Bahar	1617				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status 1)⊠	Responsive to communication(s) filed on <u>21 J</u>	anuary 2003					
2a)□		s action is non-final.					
3)	,—		ars prosecution as to the marits is				
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims							
4)⊠ Claim(s) <u>1,2,7 and 8</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1,2,7 and 8</u> is/are rejected.							
7)	Claim(s) is/are objected to.		•				
8)[	Claim(s) are subject to restriction and/or	election requirement.					
Applicati	on Papers						
9)☐ The specification is objected to by the Examiner.							
10) 🔲 🗆	Γhe drawing(s) filed on is/are: a)□ accep	ted or b) objected to by th	e Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.							
If approved, corrected drawings are required in reply to this Office action.							
12) The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C. §§ 119 and 120							
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
	1. Certified copies of the priority documents have been received.						
	2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>							
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).							
a) The translation of the foreign language provisional application has been received.							
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  Attachment(s)							
2) Notice	e of References Cited (P10-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449) Paper No(s) 2	5) Notice of In	ummary (PTO-413) Paper No(s)  formal Patent Application (PTO-152)				

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#### **DETAILED ACTION**

Applicant's response to the restriction requirement submitted January 21, 2003 is acknowledged. Applicant's election of Group I and climbazole as the booster with traverse is acknowledged.

Applicant argues that the composition claims and method claims are classified in the same class and subclass and would thus require a single search. Note that the search for method of use and composition are shown to be distinct inventions in the restriction requirement of December 12, 2002. Applicant also traverses the specie election requirement, but provides no explanation for her traverse.

Claims 1-2 and 7-8 are herein examined on the merits in so far as they read on the elected specie of climbazole.

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2 and 7-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the particular compounds listed in tables B1-B5 on pages 29-30 of the specification, does not reasonably provide enablement for "boosters" in general. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

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The specification is objected to under 35 U.S.C. 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence of absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Applicant fails to set forth the criteria that defines "a booster". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds, i.e., boosters, without undue experimentation. In the instant case, a number of "booster" examples are set forth in tables B1-B5, however, there is no explanation as to what common feature exists among the named examples. It is noted that these examples are neither exhaustive, nor define a particular class of compounds required. What common feature among these compounds exists?

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Given the wide spectrum of compounds that are represented by the lists provided in Tables B1-B5, e.g., fragrances, flavonoids, different acids, how would the skilled artisan be able to ascertain that a certain compound is a booster? The pharmaceutical/cosmetic art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all "boosters", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-2, 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The expression "booster" is indefinite. It is not clear which activities of the retinoid compound is boosted by these boosters? Further, it is not clear whether a retinoid compound could be a booster or not?

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-2 and 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granger et al. (USPN 5,716,627).

Granger et al. (USPN 5,716,627) teaches a skin-conditioning composition comprising (a) from about 0.001% to about 10% of retinol or retinyl ester, (b) from about 0.0001% to about 50% azole (e.g., climbazole), (c) from 0.0001% to about 50% of a fatty acid amide (B1 compounds herein) and (d) a cosmetically acceptable vehicle, see claim 1 and col. 2, lines 31-40. Granger also teaches the employment of azoles in an oil-in-water emulsion, see example 7 in col. 16.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising retinol, climbazole and another booster (i.e., fatty acid amides).

One of ordinary skill in the art would have been motivated to employ retinol, climbazole and another booster (i.e., fatty acid amides) in a composition because Granger teaches climbazole as one of the azoles that can be employed in its composition.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The

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examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar Patent Examiner April 1, 2003

SREENI PADMANABHAN